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WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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MEMORANDUM

Subject: Ecological Risk Assessment for Trinexapac-ethyl Proposed New Use on Rye and Rice

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Executive Summary:

The Environmental Fate and Effects Division (EFED) has evaluated a new use proposal for rice and rye for trinexapac-ethyl, which is a growth regulator/herbicide in the cyclohexane carboxylic acid class of chemicals. A table of previous actions for trinexapac-ethyl is included in Appendix A. The end use products (Palisade EC; EPA Reg. No 100-949 and Palisade 2EC; EPA Reg. No 100-1241) are emulsifiable concentrates. The proposed application rate for ground or aerial application to rye (1 application at 0.08-0.11 lb a.i./A per year or a split application¹ not to exceed 0.11 lb a.i./A per year) is the same as previously evaluated for other cereals in the most recent risk assessment for trinexapac-ethyl (USEPA, 2013 DP 409748). **Consequently, rye will not be modeled in this assessment as no risk concerns were identified in the previous assessment for cereal usage. No new data has been presented to change the cereal usage conclusions for terrestrial and aquatic organisms/plants from 2013. The 2013 assessment did not identify any concerns for honeybees based on an acute contact study; however, uncertainty of bees/terrestrial invertebrates risk concerns still exist based on the lack of chronic adult or honeybee larvae acute/chronic toxicity tests².**

The proposed application rate to flooded rice fields is a single application at 0.027-0.045 lb a.i./A per year by ground or aerial methods. **Terrestrial exposure for rice will not be assessed due to the rate being much lower than cereal for which there were no risk concerns identified in 2013.** The 2013

¹ The interval between split applications is based on Feekes, not time. The label language reads: Make the first application at Feekes 4-5 and a second application at Feekes 7. Apply no more than 7 fl. oz./A [0.11 lb a.i./A] total.

² The registrant has subsequently submitted an OECD 213 - Acute Oral Adult Honeybee Toxicity Test (MRID 49263401) which is pending a formal EFED review. Results were not used in this assessment but are presented in the Ecotoxicity section.

assessment did not identify any risks for aquatic organisms/plants at the cereal application rate. However, this new use for rice is the first use applied directly to water (flooded rice paddies) and this assessment will focus on risks to aquatic organisms. **Based on the labeled 5 day paddy water holding period direct risk concerns are identified for the proposed new use on rice for aquatic listed vascular plants. Chronic risk cannot be assessed or precluded for estuarine/marine invertebrates based on a lack of toxicity data. In the absence of chronic estuarine/marine invertebrate toxicity data, the likelihood for chronic risk concerns to marine/estuarine invertebrates was characterized based on the potential risks to freshwater invertebrates.**

Based on a study with no mortality and a non-definitive endpoint ($> 142,500 \mu\text{g a.i./L}$) the saltwater mysid is at least 21 times more sensitive to trinexapac-ethyl than the freshwater daphnid on an acute exposure basis. Given estuarine/marine invertebrates may be more than 21 times as sensitive than freshwater invertebrates on an acute basis, it is possible the same would be true on a chronic basis. Consequently, discounting chronic risk concerns to marine/estuarine invertebrates becomes more difficult as the relative sensitivity between the mysid and daphnid increases and approaches 130 times. In other words, if marine/estuarine invertebrates (*Americamysis bahia*) were about 130 times more sensitive on a chronic basis than their freshwater counterparts (*Daphnia magna*) the Agency's levels of concern would be exceeded. For this assessment it was also assumed that a rice field is drained directly into an estuary. If paddy water is first drained into fresh water or if held longer than 5 days in the rice field, then EECs relevant to marine/estuarine invertebrate chronic exposure, the uncertainty, and the likelihood of a risk concern would be lower.

Data Gaps Identified:

The following toxicity data gaps have been identified:

The 2013 assessment did not identify any concerns for honeybees based on acute contact RQs. However, the guidance for pollinator risk assessment has since been updated (USEPA 2014) and also recommends the studies below to fully assess risk to bees³. An acute adult oral toxicity test (OECD 213) has been submitted and is pending a formal review.

- Special study: Chronic oral toxicity to adult honeybees
- Special study: Chronic and acute toxicity to larval honeybees (Acute value can be obtained simultaneously with Chronic study).

In addition, there are additional chronic ecotoxicity data gaps for marine/estuarine fish and invertebrates.

- Estuarine/Marine Fish (Chronic) OPPTS 850.1400. A comparison of acute endpoints shows that freshwater fish are more sensitive to trinexapac-ethyl than estuarine/marine fish. Therefore, for this risk assessment the freshwater fish chronic toxicity value is assumed to be a protective surrogate for the estuarine/marine chronic toxicity value.
- Estuarine/Marine Invertebrate (Chronic) OPPTS 850.1350. Estuarine/marine invertebrates were more sensitive on an acute basis than their freshwater counterparts (daphnia) so chronic freshwater toxicity values could not be used as a protective surrogate as for estuarine/marine fish. Additionally, because the freshwater acute endpoint for daphnids is non-definitive an acute-to-chronic ratio was not calculated. For this assessment the uncertainty was characterized using the available toxicity information, and the justification is outlined in the Ecotoxicity and Risk Quotient Analysis sections. There is uncertainty in the chronic risk picture given the greater sensitivity (at least 21 times more sensitive) of mysids relative to daphnids on an acute basis. A chronic study would reduce this uncertainty. Based on acute toxicity data the mysid would need

³ A justification for the additional honeybee studies is provided in Appendix B.

to be about 130 more times more sensitive than the daphnid on a chronic basis to exceed the LOC for the proposed rice use.

Aquatic Estimated Environmental Concentrations for Rice Use

As a conservative screen, rice was assessed using the Tier I Rice Model v1.0 for a single application at a rate of 0.045 lb a.i./A to post emergent flooded rice fields. The Tier I Rice Model relies on an equilibrium partitioning concept to provide conservative estimates of environmental concentrations resulting from application of pesticides to rice paddies. When a pesticide is applied to a rice paddy, the model assumes that it will instantaneously partition between a water phase and a sediment phase. Neither the degradation of the pesticide, nor the mass transfer from the aqueous phase to the sediment is considered in this model. The Tier I Rice Model produces a single peak EEC for rice paddy water to calculate a risk quotient. The input parameters and model output are shown in Table 1, and the equation is provided in Table 2a. Representative Tier I Rice Model outputs are provided in Appendix C. Guidance for using the Tier I Rice Model may be found on the U.S. Environmental Protection Agency (EPA) Water Models web-page <http://www.epa.gov/oppefed1/models/water/index.htm>.

The initial Tier I screen (peak concentrations in paddy water) resulted in an exceedance of the LOC for listed vascular aquatic plant species (see Risk Quotient Analysis section). Consequently, EECs were refined (degradation was considered) by using a provisional Tier I Rice Model. The provisional model takes into account single-compartment first-order degradation by using the 90th percentile of the mean half-life for aerobic aquatic metabolism study total systems (water plus sediment). The provisional model produced peak, 5-day, and 21-day estimates in the paddy water itself and estimates receiving water concentrations averaged over 21 and 60 days after discharge. All other assumptions of the Tier I Rice Model remain in place. The additional inputs and outputs are in bold italics in Table 1 below, complete representative outputs are in Appendix B, and the equation presented in Table 2b.

Several major environmental degradates, (free acid CGA-179500, CGA-313458, an open chain cyclohexane ring, and an unidentified hydroproduct M3) exist for trinexapac-ethyl. EECs were not calculated for any of the major degradates for trinexapac-ethyl as there are no Agency-reviewed toxicity data related to aquatic species for these major degradates. Inputs to the provisional Tier I Rice model were based on a total toxic residue (TTR) approach which assumes these degradates have equivalent ecotoxicity properties as the parent. This provides a conservative approach evaluating risks to aquatic organisms.

Table 1. Tier I Rice Model Parameters

| Input Parameter | Value | Source |
|--|--|--|
| Single Application Rate lbs a.i./A [kg a.i./ha] | 0.045 [0.050] | Proposed label |
| Organic Carbon Partition Coefficient (K_{oc}) (L/kg _{oc}) | 416 | Average K_{oc} ¹ |
| <i>Aerobic Aquatic Metabolism Half-life (d)*</i> | <i>17.4</i> | <i>MRID 46809304</i> ² |
| Output | Peak Value (average 21 day value after release) | Source |
| Peak paddy EEC (µg a.i./L) | 31.68 <i>(21.9)*</i> ³ | Model output |

| Input Parameter | Value | Source |
|-------------------------|-------------------------------|--------------|
| 5-day paddy water EEC* | 25.97 (17.95) ³ | Model output |
| 21-day paddy water EEC* | 13.73 (9.49) ³ | Model output |

¹ = The average K_{oc} obtained from four values (144, 328, 581 and 609) for the acid (CGA-163935). This value was modeled because of conversion of the ester to the acid in the environment.
² = Following the Total Toxic Residue (TTR) approach, this value represents the 90th percentile confidence bound on the mean half-life of 2 values (12.3 and 14.8)
³ = Value is the average EEC over 21 days in the receiving body of water if released at the peak, after 5 days, or after 21 days in the paddy from the provisional Tier I Rice Model.
* = Values unique to provisional Tier I Rice Model

Table 2. (A)Tier 1 Rice Model Equation. (B) Provisional Tier 1 Rice Model Equation

| | |
|---|--|
| <p>A</p> $C_w = \frac{m_{ai}'}{0.00105 + 0.00013K_d}$ <p>and, if appropriate:</p> $K_d = 0.01K_{oc}$ <p>where:</p> <p>C_w = water concentration [µg/L] m_{ai}' = mass applied per unit area [kg/ha] K_d = water-sediment partitioning coefficient [L/kg] K_{oc} = organic carbon partitioning coefficient [L/kg]</p> | <p>B</p> $C_w = \frac{m_{ai}' e^{-kt}}{0.00105 + 0.00013K_d}$ <p>and, if appropriate:</p> $K_d = 0.01K_{oc}$ <p>where: C_w = water concentration [µg L⁻¹] m_{ai}' = mass applied per unit area [kg ha⁻¹] k = degradation rate constant [d⁻¹] t = time elapsed since application [d] K_d = water-sediment partitioning coefficient [L kg⁻¹] K_{oc} = organic carbon partitioning coefficient [L kg⁻¹]</p> |
|---|--|

Ecotoxicity Data

Toxicity data used in this risk assessment (aquatic organisms and plants) are presented below (Table 3, Table 4, and Table 5). Terrestrial data are not included in this assessment due to lack of risk concerns in the previous assessment. However, since the last assessment the registrant has submitted an acute oral adult honeybee study which, contingent upon the completion of the formal EFED review, presents an LD₅₀ of > 200 µg a.i./bee. That LD₅₀ value would indicate trinexapac-ethyl is practically non-toxic to honeybees. Additional aquatic studies and terrestrial toxicity data are presented in USEPA 2013.

Additionally, chronic toxicity data for estuarine/marine fish were not available for risk analysis. The 2013 risk assessment considered chronic data from freshwater fish as protective and conservative surrogate for estuarine/marine fish because freshwater fish were five times more sensitive to trinexapac-ethyl on an acute basis than estuarine/marine fish. The same approach was taken in this assessment.

Chronic toxicity data for estuarine/marine invertebrates were also not available to calculate an RQ. Data were available to consider an acute-to-chronic ratio (ACR); however, acute toxicity data for freshwater invertebrates (daphnids) were non-definitive. An ACR calculated using a non-definitive acute endpoint for freshwater invertebrates would underestimate chronic toxicity to marine/estuarine invertebrates. The previous risk assessment considered estimating chronic toxicity values using EpiSuite (for more details

see the 2013 assessment) but when comparing those estimates with available endpoints the results were poor matches. Additionally, freshwater invertebrates could not be used as a protective surrogate for estuarine/marine invertebrates as was done with fish, because estuarine/marine invertebrates were more sensitive on an acute basis (mysid) than their freshwater counterparts (daphnid). There was no observed treatment group mortality in the acute freshwater daphnid study, and the results produced a non-definitive EC₅₀. Comparing that value to the available EC₅₀ for estuarine/marine invertebrates (mysid) shows, the mysid shrimp was at least 21 times more sensitive to trinexapac-ethyl than the freshwater daphnid on an acute basis. In the absence of chronic estuarine/marine invertebrate toxicity data, the likelihood for chronic risk concerns to marine/estuarine invertebrates was characterized based on the potential risks to freshwater invertebrates.

Table 3. Summary of specific measurement endpoint values selected to evaluate risk for aquatic fish

| Assessment Endpoint | Measurement Endpoint | Selected Measurement Endpoint Value and Source | | |
|---|--|--|--|--|
| | | Species | Endpoint, Toxicity, and Effect(s) (mg a.i./L) | Chemical/Source / Study Classification |
| Survival and reproduction of freshwater fish | Acute mortality: most sensitive acute freshwater fish 96-hour LC ₅₀ | Catfish (<i>Ictalurus punctatus</i>) | LC ₅₀ = 35 Mortality, erratic swimming, loss of equilibrium | Trinexapac-ethyl technical grade, 92.2% a.i. MRID 41869507 Acceptable |
| | Chronic Early Life Stage: most sensitive NOAEC | Fathead minnow (<i>Pimphales promelas</i>) | NOAEC = 0.41 LOAEC = 0.80 Growth reduction | Trinexapac-ethyl, technical grade, 92.2% a.i. MRID 42081401 Acceptable |
| Survival and reproduction of estuarine/marine fish ⁴ | Acute mortality: most sensitive acute estuarine/marine fish 96-hour LC ₅₀ | Sheepshead minnow (<i>Cyprinodon variegates</i>) | 96-hour LC ₅₀ = 180 Erratic swimming, loss of equilibrium, darkened pigmentation, lethargy | Trinexapac-ethyl technical grade, 92.2% a.i. MRID 41869510 Acceptable |

Table 4. Summary of specific measurement endpoint values selected to evaluate risk for aquatic invertebrates

⁴ Chronic toxicity endpoint for freshwater fish used to evaluate risk for estuarine/marine fish.

| Assessment Endpoint | Measurement Endpoint | Selected Measurement Endpoint Value and Source | | |
|--|--|--|---|--|
| | | Species | Endpoint, Toxicity, and Effect(s) (mg a.i./L) | Chemical/ Source / Study Classification |
| Survival and reproduction of freshwater invertebrates ⁵ | Acute mortality: most sensitive acute freshwater invertebrate 48-hour EC ₅₀ | Waterflea (<i>D. magna</i>) | 48-hour EC ₅₀ >142.5 Immobilization, floating at water surface, erratic swimming | Trinexapac-ethyl, technical grade, 96.6% a.i. MRID 41563906 Acceptable |
| | Chronic effects: most sensitive NOAEC | Waterflea (<i>D. magna</i>) | NOAEC = 2.4 LOAEC = 5.1 Reductions in adult daphnid length | Trinexapac-ethyl, technical grade, 93.8% MRID 43128602 Acceptable |
| Survival and reproduction of estuarine/marine invertebrates | Acute mortality: most sensitive estuarine/marine invertebrate 96-hour EC ₅₀ | Mysid shrimp (<i>Americamysis bahia</i>) | EC ₅₀ = 6.5 NOAEC < 3.4 Mortality, erratic swimming, darkened pigmentation, lethargy | Trinexapac-ethyl, technical grade, 92.2% MRID 41869508 Acceptable |

Table 5. Summary of endpoints selected to evaluate risk for aquatic plants

| Assessment Endpoint | Measurement Endpoint | Selected Measurement Endpoint Value and Source | | |
|--|--|---|--|---|
| | | Species | Endpoint, Toxicity, and Effect(s) (µg a.i./L) | Chemical/ Source / Study Classification |
| Survival and biomass of aquatic vascular and non-vascular plants | Non-vascular species: the most sensitive productivity EC ₅₀ | Blue-green algae (<i>Anabaena flos-aquae</i>) | 120-hour EC ₅₀ = 350 NOAEC = 110 Cell density | Trinexapac-ethyl technical grade, 92.2% a.i. MRID 41869535 Acceptable |
| | Vascular species: the most sensitive productivity EC ₅₀ | Duckweed (<i>Lemna gibba</i>) | EC ₅₀ = 190 NOAEC = 18 Frond density | Trinexapac-ethyl technical grade, 96.6% a.i. MRID 42595303 Acceptable |

⁵ Acute toxicity data were non-definitive and not used to generate an RQ

Risk Quotient (RQ) Analysis

Risk quotients calculated from toxicity data listed above and the peak EEC ($EEC \div EC_{50}/LC_{50}$ or NOAEC) of the Tier I Rice Model for aquatic fish, aquatic invertebrates, and aquatic plants are presented in Table 6 Table 7, and Table 8 below. Even with the conservative nature of the model's peak EEC (i.e., no holding time consideration, or no degradation/loss before release into receiving waters), no acute or chronic RQs exceeded the LOCs for listed and non-listed freshwater fish. Freshwater fish were also considered a conservative and protective surrogate for estuarine/marine fish. In addition, the freshwater invertebrate RQ did not exceed the chronic LOC and the estuarine/marine invertebrate RQ did not exceed the acute LOC. A risk quotient based on acute toxicity could not be calculated for freshwater invertebrates, because the toxicity value is non-definitive. However, the most sensitive EC_{50} ($>142,500 \mu\text{g a.i./L}$) is 4 orders of magnitude higher than the peak EEC for rice ($31.68 \mu\text{g a.i./L}$). Consequently, direct risk concerns from acute exposures are not expected for freshwater invertebrates.

The RQ exceeded the Agency's LOC for listed vascular plants. All other plant categories (non-listed vascular plants and non-vascular plants) did not exceed the LOC. Based on the LOC exceedance for listed aquatic vascular plants a refining analysis was performed using the label required 5 day holding period for rice paddy water, and the provisional Rice Model was used to further characterize potential risks to both groups. Using the provisional model's peak EEC in the paddy water of $25.97 \mu\text{g a.i./L}$, a 5 day holding period would still produce an RQ (1.44) above the agency's level of concern of 1 for listed vascular plants. The model estimates on day 15 the peak EEC (17.43) in the rice water would drop low enough to produce an RQ below the Agency's LOC for listed aquatic vascular plants.

Chronic risk could not be assessed and therefore is presumed for estuarine/marine invertebrates. Toxicity data and other options (ACR, protective surrogacy) for estimating toxicity were not available (see Ecotoxicity section). The EEC ($17.95 \mu\text{g a.i./L}$) produced from the provisional Rice Model is based on a 5 day retention time in the rice field and the subsequent 21 day average concentration in the receiving body after paddy water has been discharged. A chronic toxicity NOAEC value for estuarine/marine invertebrates would have to be $\leq 17.95 \mu\text{g a.i./L}$ to exceed the Agency's LOC. Given that the freshwater invertebrate (daphnid) chronic NOAEC was $2400 \mu\text{g a.i./L}$, mysids would need to be about 130 times more sensitive to exceed the chronic LOC. The mysid is at least 21 times more sensitive than the daphnid on an acute basis. There was no mortality in the daphnid acute study which indicates the EC_{50} ($>142,500 \mu\text{g a.i./L}$) is higher. Thus, the mysid is likely more than 21 times as sensitive to trinexapac-ethyl further contributing to the chronic risk uncertainty.

Table 6. Acute and Chronic Risks from Trinexapac-ethyl to Freshwater and Estuarine/Marine Fish

| Use (Scenario) | Application Method | 1-in-10-year Aquatic RQs | | | |
|---|-----------------------|---|--|---|--|
| | | Freshwater Fish Acute RQ (Peak EEC/ EC ₅₀) EC ₅₀ = 35000 µg a.i./L | Freshwater Fish Chronic RQ (Peak EEC/ NOAEC) NOAEC = 410 µg a.i./L | Estuarine / Marine Fish Acute RQ (Peak EEC/ EC ₅₀) EC ₅₀ = 180000 µg a.i./L | Estuarine / Marine Fish Chronic RQ (Peak EEC/ NOAEC) NOAEC = 410 µg a.i./L |
| Rice – 1 app at 0.045 lb a.i./A | | | | | |
| Tier I Rice Model | N/A | <0.01 | 0.08 | <0.01 | 0.08 |
| Agency LOCs: Acute listed 0.05, Acute non-listed 0.5, Chronic (listed/non-listed) 1.0 | | | | | |

Table 7. Acute and Chronic Risks from Trinexapac-ethyl to Freshwater and Estuarine/Marine Invertebrates

| Use (Scenario) | Application Method | 1-in-10-year Aquatic RQs | |
|---|-----------------------|--|--|
| | | Freshwater Invert Chronic RQ (Peak EEC/ NOAEC) NOAEC = 2400 µg a.i./L | Estuarine / Marine Invert Acute RQ (Peak EEC/ EC ₅₀) EC ₅₀ = 6500 µg a.i./L |
| Rice – 1 app at 0.045 lb a.i./A | | | |
| Tier I Rice Model | N/A | 0.01 | <0.01 |
| Agency LOCs: Acute listed 0.05, Acute non-listed 0.5, Chronic (listed/non-listed) 1.0 | | | |

Table 8. Risks from trinexapac-ethyl to aquatic vascular and non-vascular plants

| Use (Scenario) | Application Method | 1-in-10-year Aquatic RQs | | | |
|---|-----------------------|--|--|--|---|
| | | Non-Listed Non-vascular Aquatic Plant RQ (Peak EEC/ EC ₅₀) EC ₅₀ = 350 µg a.i./L | Listed Non- vascular Aquatic Plant RQ (Peak EEC/ NOAEC) NOAEC = 110 µg a.i./L | Non-Listed Vascular Aquatic Plant RQ (Peak EEC/ EC ₅₀) EC ₅₀ = 190 µg a.i./L | Listed Vascular Aquatic Plant RQ (Peak EEC/ NOAEC) NOAEC = 18 µg a.i./L |
| Rice – 1 app at 0.045 lb a.i./A | | | | | |
| Tier I Rice Model | N/A | 0.09 | 0.29 | 0.17 | 1.76* (1.44)*^ |
| *Exceeds Agency LOC for plants: Listed/non-listed 1.0 ^ RQ calculated based on 5 day holding time peak EEC (25.97 µg a.i./L) | | | | | |

Overall Ecological Risk Conclusions

No risk concerns are identified for the proposed new uses of trinexapac-ethyl on rice. Modeling based on the labeled 5 day paddy water holding period for the proposed new use on rice, suggests direct risk concerns for listed aquatic vascular plants. Indirect effects are possible for all taxa (birds, mammals, reptiles, amphibians, fish, aquatic and terrestrial invertebrates) of listed species that depend on an aquatic vascular plant during some phase of their life-cycle for things such as food, shelter, and/or reproductive habitats. Additionally, for rice usage, chronic risk cannot be precluded for estuarine/marine invertebrates based on lack of available chronic toxicity data and the characterization of marine/estuarine risk based on freshwater invertebrate toxicity. Based on a 5 day holding period for rice paddy water and characterizing risk concerns from available freshwater invertebrate data, marine/estuarine invertebrates would have to be about 130 times more sensitive on a chronic basis than their freshwater counterparts to exceed the Agency's levels of concern. A lack of mortality in the acute toxicity study indicates the EC₅₀ could be a larger number than 142500 µg a.i./L (the value used in this assessment). Thus, sensitivity (21 times more sensitive than freshwater) of estuarine/marine invertebrates could actually be greater due to the larger discrepancy between EC₅₀ values for the mysid (6500 µg a.i./L) and the daphnid (>142500 µg a.i./L). Given estuarine/marine invertebrates may be more than 21 times as sensitive than freshwater

invertebrates on an acute basis, it is possible the same would be true on a chronic basis. Consequently, discounting chronic risk concerns to marine/estuarine invertebrates becomes more difficult as the relative sensitivity between the mysid and daphnid increases and approaches 130 times. Holding times greater than 5 days would be less likely to result in a risk concern, due to the decreasing chemical concentration in the rice field prior to release.

References:

USEPA. 2013. Ecological Risk Assessment and Effects Determination Registration Review for Trinexapac-Ethyl. Data Package Barcode: 409748. Environmental Fate and Effects Division, Office of Pesticide Programs, United States Environmental Protection Agency.

USEPA. 2014. Guidance for Assessing Pesticide Risks to Bees. Environmental Fate and Effects Division, Office of Pesticide Programs, United States Environmental Protection Agency.

MRID 46809304. Muller-Kallert, H. (1993) [(Carbon 14)] CGA 163935: Degradation and Metabolism in Aquatic Systems: Final Report. Project Number: 315426, T001447/06. Unpublished study prepared by RCC Umweltchemie Ag. 87 p. Relates to L0001034.

Appendix A: Historic Actions Table for Trinexapac-ethyl

Previous Actions and Assessed Uses for Trinexapac-ethyl (PC 112602)

| Use Site | Max. Application Rate (lb a.i./A) | | Number of applications (Application Interval in Days) | Action/DP Barcode/Date | Comments |
|--------------------------------|-----------------------------------|------------------|---|--|--|
| | Single (App Method) | Seasonal/ Annual | | | |
| All Uses (Registration Review) | N/A | N/A | N/A | DWA D409833 3/11/2013 | No new actions since previous DWAs and therefore a new DWA in support of registration review was not necessary. |
| Cereals, | 0.05- 0.11 (G/A/C) | 0.11 | 1-2 (NS) | Section 3 New Uses D377923, D377924, D377925 (Sub-387340) 12/13/11 | LOC exceedances did not occur for any of the proposed use rates for all taxonomic groups except plants. LOC was exceed for non-listed and listed monocots and dicots at ≥ 31 lb a.i./A use rates. |
| Sugarcane, | 0.06-0.31 (G/A/C) | 0.31 | 1-2 (NS) | | |
| Grasses (grown for seed) | 0.25-0.5 (G/A/C) | 0.5 | 1-2 (7-10) | | |
| Turf | 0.34 (G) | 2.7 | 8 (NS) | Tier II DWA D377936/D395601 (Parent/Sub-folder) 10/28/11 | Application interval of 7 days for modeling selected to represent actively growing turf as written on the label. |
| Cereals (Wheat, Barley, Oats), | 0.11 (G/A/C) | 0.11 | 1 | Tier II DWA DP377936/D432768 8/9/11 | |
| Sugarcane | 0.31 (G/A/C) | 0.31 | 1 | | |
| Wheat Triticale (R2084954) | 0.11 (A) | 0.11 | 1 | Section 18 Emergency Use Exemption Extension Oregon | LOC exceedances are not likely to occur for proposed use rate. |

| | | | | | |
|---|--|-------|------------------------------------|---|---|
| | | | | D375141 4/1/10 | |
| Turf (R2080374) | 0.34 (A) 0.68 (A) 1.36 (A) | 2.72 | 8 (28) 4 (56) 2 (56) | Registration Review. Preliminary Problem Formulation D351403 5/20/08 | RQ exceeds level of concern for chronic avian dietary (0.68 lbs a.i./A and greater) and acute and chronic for semi-aquatic plants. |
| Perennial ryegrass (ID, OR, WA) | 0.195-0.455 | 0.49 | 1-2 (NS) | | |
| Perennial Ryegrass, Fine and Tall Fescues, Ryegrass (MN) | 0.187-0.49 | 0.49 | 1-2 (NS) | | |
| Turf grasses (Primo Product) (R2070950) | 0.6875 | 2.675 | 3.9 (14) | Section 18 Emergency Use Exemption Extension 38 States D171357 3/10/92 | |
| Turf grasses (Vision Product) | 0.75 | 2.675 | 3.6 (56) | | |

N/A= Not applicable, NS = Not specified, DWA = Drinking Water Assessment
G = ground, A = aerial, C = chemigation

Appendix B: Justification for Additional Honeybee studies

Adult Chronic Toxicity Study

Bees can be exposed to pesticides through multiple pathways including contact with sprays and dusts and through ingestion of residues in food/water (*e.g.*, pollen/nectar and water used to maintain colony temperature). Worker bees foraging on flowers for pollen and nectar can be repeatedly exposed to residues in pollen and nectar either through direct contamination of these matrices by foliar sprays and/or dusts or through translocation of residues via systemic transport of the active ingredient. Residues can in turn be brought back to bee colonies where in-hive bees including young adult and developing brood (*i.e.*, eggs, larvae and pupae) may be exposed. EPA guidance (USEPA 2014) on assessing the risk of pesticides to bees identifies a suite of laboratory-based studies intended to serve as the foundation for screening chemicals for potential acute and chronic exposure effects to individual adult and larval bees. The 10-day toxicity study with young adult bees provides no-observed adverse effect level (NOAEL) and lowest-observed adverse effect level (LOAEL) for assessing chronic effects. Data obtained from this study will be used in estimating chronic risk to individual adult bees. This is a non-guideline study; an OECD protocol is expected to be available in October 2014. A protocol should be submitted to the Agency for review before commencing the study and should include provisions for measuring the concentration of trinexapac-ethyl in the actual diet of the honeybee.

Larval Toxicity Study

Developing bee brood (*i.e.*, larvae and pupae) can be exposed to pesticides through residues brought back to the colony by worker bees foraging in areas where the pesticide has been applied. While larvae are typically fed royal or brood jelly during their early stages of

development, worker bee (females) and drone (males) larvae are also fed pollen/honey (bee bread) directly by in-hive nurse bees. EPA guidance (USEPA 2014) on assessing the risk of pesticides to bees identifies a suite of laboratory-based studies intended that serve as the foundation for screening chemical for potential acute and chronic effects to individual adult and larval bees. The 21-day larval toxicity study under development by OECD provides both acute and chronic toxicity data on developing bee brood and will yield a median lethal dose (LD₅₀) for assessing acute toxicity during the early part of the study as well as a 21-day no-observed adverse effect level (NOAEL) and lowest-observed adverse effect level (LOAEL) for assessing chronic effects. Alternatively, registrants may submit a separate acute (single dose) larval toxicity study following OECD Guideline 237 as well as the 21-day repeat dose chronic toxicity study to address both acute and chronic larval endpoints. Effects on survival and development (adult bee emergence) from repeat exposures to the active ingredient will be used in estimating chronic risk to individual brood. A protocol for the 21-day larval toxicity test should be submitted to the Agency for review before commencing the study and should include provisions for measuring the concentration of trinexapac-ethyl in the actual diet of the honeybee.

Appendix C: Model Outputs

Tier I Rice Model Output

| | |
|-----------------------------------|-------------------|
| App Rate (lbs. a.i./A) | 0.045 |
| App Rate Conversion (kg. a.i./ha) | 0.0504 |
| Koc | 416 |
| Kd | 4.16 |
| Peak EEC | 31.68 ug/L |

Provisional Tier I Rice Model Output

Eco EECs

| Holding Time | Peak | 21-d Mean | 60-d Mean | Annual Mean |
|--------------|-------|-----------|-----------|-------------|
| Paddy | 31.69 | 21.90 | 12.29 | 2.22 |
| 5-d Tail | 25.97 | 17.95 | 10.07 | 1.82 |
| 15-d Tail | 17.44 | 12.05 | 6.76 | 1.22 |
| 21-d Tail | 13.73 | 9.49 | 5.32 | 0.96 |

